

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

| | | |
|---|---|------------------------|
| NIPPON SHINYAKU CO., LTD., Plaintiff, |) | |
| |) | |
| v. |) | |
| |) | C.A. No. 21-1015 (GBW) |
| SAREPTA THERAPEUTICS, INC., |) | |
| Defendant. |) | |
| |) | |
| |) | |
| SAREPTA THERAPEUTICS, INC., and |) | |
| THE UNIVERSITY OF WESTERN |) | |
| AUSTRALIA, Defendant and Counter- |) | [REDACTED] |
| Plaintiffs |) | |
| |) | |
| v. |) | |
| |) | |
| NIPPON SHINYAKU CO., LTD. and |) | |
| NS PHARMA, INC., Plaintiff and Counter- |) | |
| Defendants. |) | |

**NIPPON SHINYAKU CO. LTD. AND NS PHARMA, INC.’S MOTION FOR THE
ISSUANCE OF A REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE
AND INCORPORATED MEMORANDUM OF LAW IN SUPPORT**

Plaintiff/Counter-Defendant Nippon Shinyaku Co. Ltd. and Counter-Defendant NS Pharma, Inc. (collectively, “NS”) respectfully move, pursuant to Federal Rule of Civil Procedure 28 and Article 3 of the Hague Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters, 28 U.S.C. § 1781 (the “Hague Convention”), the Court to issue the attached Letter of Request (**Exhibit A**) to the Competent Authority of Australia to compel the testimony of Sue Fletcher, who, upon information and belief, is a citizen of and reside in Australia.

I. BACKGROUND

This patent infringement action involves antisense oligonucleotides (“ASOs”) for the treatment of Duchenne’s muscular dystrophy (“DMD”). Nippon Shinyaku, Co., Ltd. (“Nippon Shinyaku”) and NS Pharma, Inc. (“NS Pharma,” collectively with Nippon Shinyaku “NS”) are direct competitors of Sarepta Therapeutics (“Sarepta”—each provide ASO-based therapies for the treatment of DMD. Sarepta and NS are the only companies with FDA clearance to market ASO therapies that induce exon 53-skipping for the treatment of DMD for patients in need thereof. Sarepta’s product is marketed under the name VYONDYS 53, and NS’s product is marketed under the name VILTEPSO®.

Nippon Shinyaku initiated this action alleging that Sarepta’s manufacture, use, and sale of VYONDYS 53 infringed its U.S. Patent Nos. 9,708,361, 10,385,092, 10,407,461, 10,487,106, 10,647,741, 10,662,217, and 10,683,322 (collectively the “NS patents”) (Second Am. Compl. ¶¶ 3, 92-164, D.I. 86.) Nippon Shinyaku also sought a declaratory judgment of invalidity University of Western Australia’s (“UWA”) U.S. Patent Nos. 9,994,851, 10,227,590, and 10,266,827 (collectively the “UWA patents”), which are licensed to Sarepta. (*Id.* ¶¶ 2, 76-91.) Sarepta and UWA filed counterclaims seeking a declaratory judgment of invalidity the NS patents and alleging that NS’s manufacture, use, and sale of VILTEPSO® infringed the UWA patents. (Am. Answer to Second Am. Compl. ¶¶ 1-2, 36-81, D.I. 195). NS denies infringement and alleges that the UWA Patents are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 et seq. relating to requirements for patentability. (Answer to Countercl. ¶¶ 1-2, 36-81, D.I. 200.)

The UWA patents name Drs. Stephen Donald Wilton, Sue Fletcher, and Graham McClorey as inventors. (Second Am. Compl. ¶ 49.) [REDACTED]

[REDACTED]

[REDACTED] Neither Sarepta nor UWA has produced any laboratory notebooks, emails, memos, or notes from Dr. Fletcher showing her role in exon 53-skipping research.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In preparing this request for international judicial assistance, NS requested Sarepta and UWA’s confirmation that it would not oppose this Motion. This motion is opposed by Sarepta and UWA.

II. LEGAL STANDARD

Australia and the United States are both signatories to the Hague Convention, which “prescribes certain procedures by which a judicial authority in one contracting nation may request evidence located in another nation.” *In re Automotive Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 299 (3d Cir. 2004). Under Chapter 1, Article 1, these procedures provide that a domestic court may issue a “letter of request” to a foreign court for execution. Federal courts are inherently vested with authority to issue letters of request. *See* 28 U.S.C. § 1781.

While issuance of a letter of request is within the Court’s discretion, the “burden is not great for a party seeking a letter of request” and are “routinely issue[d] . . . where the movant makes a reasonable showing that the evidence sought may be material or may lead to the discovery of material evidence.” *Compagnie des Grands Hotels d’Afrique S.A. v. Starman Hotel Holdings LLC*, C.A. No. 18-00654-RGA, 2019 WL 3391971, at *2 (D. Del. July 26, 2019)

(internal quotation marks, citation omitted). Courts consider five factors in determining whether issuance of a letter of request give due respect to international comity:

(1) the importance of the documents or information requested to the litigation; (2) the degree of specificity of the requests; (3) whether the information originated in the United States; (4) the availability of alternative means of securing the information; and (5) the extent to which noncompliance with the requests would undermine important interests of the United States, or compliance of the requests would undermine important interests of the state where the information is located.

Liqwd, Inc v. L’Oreal USA, Inc., Civ. No. 17-14-JFP-SRF, 2018 WL 11189616, at *2 n.1 (D. Del Nov. 16, 2018) (citing *Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Ct., D. Iowa*, 482 U.S. 522, 543-44 (1987)).

III. ARGUMENT

NS seeks to take evidence from an inventor of the UWA patents through issuance and execution of the attached letter of request. On information and belief, the individual is an Australian national who currently resides within Australia and is subject to the jurisdiction of the Australian courts.

NS is unable to obtain testimony from Dr. Fletcher through available U.S. procedures (e.g., a subpoena pursuant to Fed. R. Civ. P. 45). Dr. Fletcher is a percipient fact witness who possess information related to [REDACTED]

[REDACTED]—issues directly relevant to the parties’ dispute and material to NS’s claims and defenses. Despite being a named inventor, [REDACTED]
[REDACTED]
[REDACTED]

The letter of request does not place an undue burden on Dr. Fletcher. The topics for examination are narrowly tailored to seek the witness’ documents related to her research of ASOs

for inducing exon-53 skipping and the witness' testimony of her personal knowledge concerning the aforementioned issues and do not otherwise seek information on tangential matters to this case.

The *Aerospatiale* comity factors weigh in favor of granting NS's Motion

The information sought from Dr. Fletcher is essential to NS's defenses and counterclaim of inequitable conduct. In granting Sarepta's request to depose an inventor of the NS Patents, Special Master Squires acknowledged that inventors possess knowledge relevant to the claimed subject matter of the asserted patents. (D.I. 254 at 9.) For example, Dr. Fletcher's documents and testimony is highly relevant to: (1) her possible inventorship, conception, and reduction to practice of the claimed subject matter in the asserted UWA patents; (2) the actual timing of the conception, including recognition and appreciation, and reduction to practice of the claims of the asserted UWA patents; and (3) the validity of the UWA patents under 35 U.S.C. § 112. *See, e.g., Dyson, Inc. v. SharkNinja Operating, LLC*, No. 1:14-cv-0779, 2016 WL 5720702, at* 2 (N.D. Ill. Sept. 30, 2016) ("Issues related to inventorship, conception, and reduction to practice are central to the validity of the patents").

The importance of the documents and testimony is also supported and demonstrated

The image consists of eight horizontal black bars arranged vertically. Each bar is a solid black rectangle. The length of each bar decreases progressively from the top bar to the bottom bar. The top bar is the longest, followed by a slightly shorter one, then a medium-length one, and so on down to the shortest bar at the bottom. The bars are set against a plain white background.

[REDACTED] It is thus likely that Dr. Fletcher also has relevant documents.

NS's request is tailored to testimony and documents relating to NS's claims and defenses. NS seeks documents from Dr. Fletcher relating to her involvement in the research of ASOs for exon 53 skipping. NS also seeks to depose Dr. Fletcher relating to her *personal knowledge* of facts related to her employment with UWA and/or Perron Institute, the Wilton/Fletcher laboratory, and her work related to DMD and ASOs targeting exon 53. NS's requests to depose Dr. Fletcher are directly related to NS's challenge to the validity and enforceability of the UWA patents and its pending inequitable conduct defense and counterclaim. Accordingly, this factor weights in favor of granting NS's Motion. *See, e.g., Luminati Networks Ltd. v. Teso LT, UAB*, No. 2:19-CV-00395-JRG, 2020 WL 6815153, at *1 (E.D. Tex. Oct. 28, 2020) (finding specificity factor weighed in favor of granting motion for issuance of letters rogatory where testimony sought related to claims in case).

NS cannot obtain the information from other sources. Dr. Fletcher is not a party to the lawsuit, has not voluntarily subjected herself to discovery, and is not otherwise subject to the jurisdiction of the Court. *Tulip Computers Int'l B.V. v. Dell Computer Corp.*, 254 F. Supp. 2d 469, (D. Del. 2003). Special Master Squires denied NS's motion to compel the deposition of Dr. Fletcher because Dr. Fletcher is not a UWA or Sarepta employee and does not have a contractual obligation to testify. (D.I. 254 at 12-13.) Other than [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

[REDACTED]
[REDACTED]
[REDACTED]
NS could not obtain this information from Dr. Wilton at his deposition. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] NS would still be entitled to seek her deposition because she is a named inventor and, according to Sarepta, UWA, and Dr. Wilton, contributed to the conception, and reduction to practice of the asserted claims of the UWA patents. *See Dyson*, 2016 WL 5720702 at *2. “There is no guarantee that [Dr. Fletcher] will have the same memory of the invention process [as Dr. Wilton], and [NS] should not have to take [Sarepta’s] word for it.” *Id.* Accordingly, this factor weighs in favor of granting NS’s Motion.

The national interests also weigh in favor of granting NS’s Motion. The United States has an important interest “ensuring that patent suits are fully and fairly litigated.” *Dyson*, 2016 WL 5720702, at *3. The United States also has a strong interest “in a defendant being able to exercise its discovery rights and its right to prepare a defense.” *Arcelik A.S. v. E.I. Dupont de Nemours & Co.*, 856 F. App’x 392, 399 (3d Cir. 2021). Moreover, Australia “will ultimately decide about . . . specific questions,” and thus compliance with the request would not undermine any of Australia’s important interests. *Id.* at 400.

Four of the five *Aerospatiale* factors weigh in favor of Granting NS’s Motion. Although the testimony relates to information that originated outside of the United States—Dr. Fletcher performed her work in Australia—this is “overcome by the fact that there [are] no alternative means for [NS] to obtain the information” and because their testimony is vital to NS’s claims

related to inventorship, conception, and reduction to practice of the UWA Patents. *See id.* at 399.

The Court should therefore grant NS's Motion

IV. CONCLUSION

As set forth above, the requested oral examinations are relevant to NS's claims and defenses, and issuance of this letter of request serves the interests of justice. NS respectfully requests that its Motion be granted and that the Court sign and issue the letter of request attached as Exhibit A. Once the Court has done so, counsel for NS shall convey the signed letter to the Supreme Courts in Australia for execution.

Dated: July 19, 2023

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS

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CERTIFICATE OF SERVICE

I certify that on July 19, 2023, I caused a true and correct copy of the foregoing document to be served on the counsel of record listed below via e-mail:

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